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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,057	11/21/2000	Michael Brines	10165-010-999	5119

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EXAMINER
DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
1647	16

DATE MAILED: 11/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/717,057	BRINES ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspond nce addr ss --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *8 and 11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-11* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6,9,1114* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Status of Application, Amendments and/or Claims

The amendment filed 22 February 2001 (Paper No. 5) has been entered in full. The information disclosure statement filed 22 February 2001 (Paper No. 6) was received and complies with the provisions of 37 CFR §§1.97 and 1.98. The information disclosure statement filed 16 October 2001 (Paper No. 9) was received and complies with the provisions of 37 CFR §§1.97 and 1.98. The information disclosure statement filed 04 March 2002 (Paper No. 11) was received and complies with the provisions of 37 CFR §§1.97 and 1.98. The information disclosure statement filed 16 August 2002 (Paper No. 14) was received and complies with the provisions of 37 CFR §§1.97 and 1.98. They have been placed in the application file and the information referred to therein has been considered as to the merits.

Applicant's election with traverse of Group XVII (claims 1-7, 9 and 10, drawn to a method comprising administering recombinant form of EPO) and species election of cognitive dysfunction and central nervous system in Paper No. 15 is acknowledged. The traversal is on the grounds that the eighteen restriction groups required by the Examiner do not represent independent, separately patentable inventions but, rather, are properly characterized as species of a single generic invention. Applicant states that the Groups are functionally identically in that they recite methods of administering species of EPOs and EPO-like compounds which are capable of interacting with the EPO receptors of epithelial tights junctions, including the eighteen designated species of compounds with this functional characteristic in common. Applicants state that the eighteen groups represent a single species of a single invention. Applicants state that a

search of all of the methods of the invention would not constitute an undue burden, since many of these species comprise structurally identical compounds and fall into a number of other groups.

Contrary to Applicants assertion, the methods are drawn to administering different compositions such as analogs, multimers, EPO agonists, muteins and congeners. The instant compositions may differ from erythropoietin both structurally and functionally. The term "EPO-receptor activity modulator" or "EPO-activated receptor modulator" can encompass various chemical compositions. A search of all of the methods of the invention would constitute an undue burden because of the diverse nature of the EPO compositions claimed.

The traversal is also on the grounds that it would not be a serious burden on the Examiner to search any relevant art for to the diseases recited in Claim 3 and the excitable tissue recited in Claim 4 because the search for these elements should have already been carried out in the search for relevant art related to Claim 1. This is not found persuasive. Contrary to Applicant's assertion, a search is directed to references which would render the invention obvious, as well as references directed to anticipation of the invention, and therefore requires a search of relevant literature in many different areas of subject matter. Claim 1 is drawn to enhancing the function of normal or abnormal excitable tissue, a search for enhancing the function of normal tissue would not pick up many of the conditions recited in Claim 3. In addition, the excitable tissues recited in Claim 4 are so broad that a search would encompass many different areas

and would not necessarily pick up the conditions in Group II or would perhaps after an exhaustive search.

The requirement is still deemed proper and is therefore made FINAL. Claims 8 and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 15.

Priority

If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed on or after November 29, 2000, any claim for priority must be made during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2) and (a)(5). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and

365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) a surcharge under 37 CFR 1.17(t), and (2) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method for enhancing the function of normal excitable tissues in a mammal, wherein enhancing the function of said normal excitable tissue results in enhancement of associative learning or memory in a mammal comprising administering peripherally to said mammal a peripherally effective excitable tissue enhancing amount of EPO

does not reasonably provide enablement for a method for enhancing the function of abnormal excitable tissue in a mammal comprising administering peripherally to said mammal a peripherally effective excitable tissue enhancing amount of an EPO. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification teaches the enhancement of learning and memory in **normal** rats with **normal excitable tissue** (Examples 1 and 2). The claims however encompass enhancement of function of abnormal excitable tissue and cognitive dysfunction. The specification does not teach enhancing the function of abnormal excitable tissue in mammals. The specification does not disclose examples where the function of abnormal excitable tissue in rats suffering from conditions such as memory loss or disturbances in mental processes related to thinking, reasoning or judgment is enhanced upon administering EPO.

Due to the large quantity of experimentation necessary to enhance the function of abnormal excitable tissue in a mammal, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention and the breadth of the claims which fail to recite limitations regarding excitable tissue, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "effective excitable tissue enhancing amount" is an ambiguous term and therefore the metes and bounds of the instant claim cannot be determined.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 09/547,220. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1 of the instant application is drawn to a

method for enhancing the function of normal or abnormal excitable tissue in a mammal comprising administering peripherally to said mammal a peripherally effective excitable tissue enhancing amount of EPO. Claim 1 of application 09/547,220 is drawn to a method for treating cerebral ischemia in a mammal comprising peripherally administering to said mammal a non-toxic amount of erythropoietin to said mammal effective to exert a neuroprotective effect. The specification defines "excitable tissue" as neuronal and cardiac tissue (page 1, lines 13-14). The method of claim 1 of the instant application would encompass cerebral ischemia (brain) (page 5, lines 18-35). Thus the species of treating cerebral ischemia in a mammal comprising peripherally administering to said mammal a non-toxic amount of EPO renders a method of enhancing the function of abnormal excitable tissue in a mammal comprising administering peripherally to said mammal a peripherally effective excitable tissue enhancing amount of EPO obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 09,717,053. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1 of the instant application is drawn to a method for enhancing the function of normal or abnormal excitable tissue in a mammal comprising administering peripherally to said mammal a peripherally effective excitable

tissue enhancing amount of an EPO. Claim 1 of application 09/717,053 is drawn to a method for the prevention or treatment of a neuromuscular or muscular condition comprising administering peripherally to said mammal an effective amount of EPO for the protection of a heart disease. The specification defines "excitable tissue" as neuronal and cardiac tissue (page 1, lines 13-14). A method for enhancing the function of abnormal excitable (neuronal or cardiac) tissue would encompass treating neuromuscular or muscular conditions. Thus the claims overlap as both comprise administering peripherally the same agent and are drawn broadly to treatment of an overlapping patient population.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 09,716,960. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1 of the instant application is drawn to a method for enhancing the function of normal or abnormal excitable tissue in a mammal comprising administering peripherally to said mammal a peripherally effective excitable tissue enhancing amount of an EPO. Claim 1 of application 09/716960 is drawn to a method for the prevention or treatment of a neurodegenerative condition comprising administering peripherally to said mammal an effective amount of EPO. The specification defines "excitable tissue" as neuronal and cardiac tissue

(page 1, lines 13-14). Enhancing the function of abnormal excitable (neuronal) tissue would encompass treating neurodegenerative conditions. Thus the claims overlap as both comprise administering peripherally the same agent and are drawn broadly to treatment of an overlapping patient population.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Grimm *et al.* (Kidney International, Vol. 38 (1990) pages 480-486, cited in IDS#BC, Paper No. 6). Grimm teaches that administering recombinant human erythropoietin in hemodialysis patients can improve brain function. Grimm teaches administering rhuEPO (recombinant human erythropoietin) to a human. The rhEPO was administered intravenously (peripherally) and vascularly (page 480, 4th paragraph Methods).

Claims 1-7, 9 and 10 rejected under 35 U.S.C. 102(b) as being anticipated by Marsh *et al.* (Kidney International, Vol. 39 pages 155-163, 1991, cited in IDS#BP, Paper

No. 6). Marsh teaches that recombinant human EPO treatment improves brain and cognitive function of anemic dialysis patients.

Amending the instant claims to recite an amount of EPO that does not increase hemoglobin concentration or hematocrit in a mammal will obviate the 102(b) rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on Mondays-Fridays 8:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

RMD
October 21, 2002